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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/866,067	05/23/2001	Thomas J. Meade	A-58762-20/RFT/RMS/RMK	7813

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EXAMINER

LU, FRANK WEI MIN

ART UNIT PAPER NUMBER

1634

DATE MAILED: 02/23/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

09/866,067

**Applicant(s)**

MEADE ET AL.

**Examiner**

Frank W Lu

**Art Unit**

1634

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 20 January 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 21-32 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 21-32 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 23 May 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.  
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_. 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

#### **CONTINUED EXAMINATION UNDER 37 CFR 1.114 AFTER FINAL REJECTION**

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission of RCE and the amendment filed on January 20, 2006 have been entered. The claims pending in this application are claims and 21-32. Rejection and/or objection not reiterated from the previous office action are hereby withdrawn in view of amendment filed on January 20, 2006.

#### ***Claim Objections***

2. Claim is objected to because of the following informality: "said nucleotide" should be "said nucleotide triphosphate".

Appropriate correction is required.

#### ***Claim Rejections - 35 USC § 112***

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. New Matter

Art Unit: 1634

Claims 21-32 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Although the specification describes 2' or 3' modified nucleotide triphosphate (see page 21, last paragraph) and deoxyribonucleoside triphosphates (see specification, page 40, first paragraph), the specification does not adequately describe that a nucleotide triphosphate comprising a covalently attached electron transfer moiety comprising a transition metal complex and at least one ligand as recited in claims 21-32. MPEP 2163.06 states that "If new matter is added to the claims, the examiner should reject the claims under 35 U.S.C. 112, first paragraph - written description requirement. *In re Rasmussen*, 650 F.2d 1212, 211 USPQ 323 (CCPA 1981)." In view of the embodiments adequately description in the specification, the subject application does not reasonably convey to one skilled in the art that applicant was in possession of the full scopes of products encompass in the claims at the time of the application was filled. Therefore, the written description requirement has not been satisfied.

In support of this position, attention is directed to the decision of *Vas-Cath inc. V.*

*Mahurkar* 19 USPQ2d 1111 (CAFC, 1991):

This court in *Wilder* (and the CCPA before it) clearly recognized, and we hereby reaffirm, that 35 U.S.C. 112, first paragraph, requires a "written description of the invention" which is separate and distinct from the enablement requirement. The purpose of the "written description" requirement is broader than to merely explain how to "make and use"; the "applicant must also convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the "written description" inquiry, *whatever is now claimed*.

***Response to Arguments***

In page 4, four paragraph bridging to page 6, third paragraph of applicant's remarks, applicant argues that "[T]he Applicants respectfully submit that the specification describes nucleotide triphosphates with covalently attached ETMs. As the Examiner admits, the specification teaches 2' or 3' modified nucleotide triphosphates. The Applicants respectfully point out that the 'modification' at the 2' or 3' position is in fact the covalent attachment of an ETM. For example, Figures 4A and B show nucleosides with covalently attached (e.g. 2' or 3' modified) ETMs. The specification then describes using these nucleosides to form nucleotide triphosphates. See for example page 21, lines 29 - 33: 'the amino modified nucleotides made as described above are converted to the 2' or 3' modified nucleotide triphosphate from using standard biochemical methods', citing Fraser. The applicants submit that the conversion of ETM modified nucleosides to triphosphate form is described in the specification, and the reaction to take nucleosides and add the triphosphate group was well known in the art, including modified nucleosides".

These arguments have been fully considered but they are not persuasive toward the withdrawal of the rejection. First, since it is known that Ru is +2 or +3 in  $\text{RuCl}_2$  or  $\text{RuCl}_3$  and forms a ionic bond with Cl, and the specification does not adequately describe that the bond between Ru and NH in Figure 4B is a covalent bond, applicant's statement "Figures 4A and B show nucleosides with covalently attached (e.g. 2' or 3' modified) ETMs" is questionable. Second, covalently attached electron transfer moiety recited in claims 21 and 27 is not limited to

Art Unit: 1634

covalently attach electron transfer moiety to 2' or 3' ribose of a nucleotide triphosphate as suggested by applicant.

5. Enablement

Claims 21, 24-27, and 30-32 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for using a nucleotide triphosphate recited in claims 21, 24-27, and 30-32 as a nucleotide triphosphate when said electron transfer moiety is attached to the ribose of said nucleotide, does not reasonably provide enablement for using a nucleotide triphosphate recited in claims 21, 24-27, and 30-32 to produce nucleotide diphosphate such as ADP when the transition metal forms two covalent bonds with the second and third phosphates of the nucleotide triphosphate. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

In *In re Wands*, 858 F.2d 731,737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988) the court considered the issue of enablement in molecular biology. The Court summarized eight factors to be considered in a determination of "undue experimentation". These factors include: (a) the quantity of experimentation necessary; (b) the amount of direction or guidance presented; (c) the presence or absence of working examples; (d) the nature of the invention; (e) the state of the prior art; (f) the relative skill of those in the art; (g) the predictability of the art; and (h) the breadth of the claims. The Court also stated that although the level of skill in molecular biology is high, results of experiments in molecular biology are unpredictable.

Art Unit: 1634

To begin, there is no direction or guidance in the specification to show that a nucleotide triphosphate recited in claims 21, 24-27, and 30-32 can produce nucleotide diphosphate such as ADP when transition metal forms two covalent bonds with the second and third phosphates of the nucleotide triphosphate. While the relative skill in the art is very high (the Ph.D. degree with laboratory experience), there is no predictability whether a nucleotide triphosphate recited in claims 21, 24-27, and 30-32 can produce nucleotide diphosphate such as ADP when the transition metal forms two covalent bonds with the second and third phosphates of the nucleotide triphosphate.

Since claims 21 and 27 do not require that the electron transfer moiety is attached to the ribose of the nucleotide triphosphate, the nucleotide triphosphate recited in claims 21, 24-27, and 30-32 is read as a nucleotide triphosphate comprising a covalently attached electron transfer moiety comprising a transition metal and at least one ligand wherein the electron transfer moiety is covalently attached to any part of the nucleotide triphosphate which includes a nucleotide triphosphate comprising a covalently attached electron transfer moiety comprising a transition metal and at least one ligand wherein the transition metal forms two covalent bonds with the second and third phosphates of the nucleotide triphosphate. When the nucleotide triphosphate recited in claims 21, 24-27, and 30-32 is a nucleotide triphosphate comprising a covalently attached electron transfer moiety comprising a transition metal and at least one ligand wherein the transition metal forms two covalent bonds with the second and third phosphates of the nucleotide triphosphate, the third phosphate of the nucleotide triphosphate recited in claims 21, 24-27, and 30-32 cannot be released to produce a nucleotide diphosphate such as ADP so that

Art Unit: 1634

the nucleotide triphosphate recited in claims 21, 24-27, and 30-32 cannot produce nucleotide diphosphate such as ADP and lose a function as a nucleotide triphosphate.

With above unpredictable factor, the skilled artisan will have no way to predict the experimental results. Accordingly, it is concluded that undue experimentation is required to make the invention as it is claimed. The undue experimentation at least includes to test whether a nucleotide triphosphate comprising a covalently attached electron transfer moiety comprising a transition metal and at least one ligand wherein the transition metal forms two covalent bonds with the second and third phosphates of the nucleotide triphosphate can produce nucleotide diphosphate such as ADP.

### ***Claim Rejections - 35 USC § 102***

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claim 21 is rejected under 35 U.S.C. 102(b) as being anticipated by Tribolet *et al.*, (Inorg. Chem., 26, 638-643, 1987).

Regarding claim 21, since according to the specification, “electron donor moiety” and “electron acceptor moiety” are “molecules capable of electron transfer under certain conditions. It is to be understood that electron donor and acceptor capabilities are relative; that is, a molecule which can lose an electron under certain experimental conditions will be able to accept an electron under different experimental conditions” (see the specification, page 15, lines 6-15),



Art Unit: 1634

phosphate is electron donor moiety. Since Sigel *et al.*, teach a  $\text{Cd}(\text{ATP})(\text{NH}_3)^{2-}$  complex wherein Cd attaches to ATP by phosphate (see page 639, right column) and Cd is a transition metal, Sigel *et al.*, teach a nucleotide triphosphate comprising a covalently attached electron transfer moiety (ie., phosphate) comprising a transition metal complex (ie., Cd) and at least one ligand (ie.,  $(\text{NH}_3)^{2-}$ ).

Therefore, Tribolet *et al.*, teach all limitations recited in claim 21.

### ***Conclusion***

8. No claim is allowed.

9. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993)(See 37 CAR § 1.6(d)). The CM Fax Center number is (571)273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frank Lu, Ph.D., whose telephone number is (571)272-0746.

The examiner can normally be reached on Monday-Friday from 9 A.M. to 5 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones, can be reached on (571)272-0745.

Art Unit: 1634

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Frank Lu  
Primary Examiner  
February 17, 2006



*Primary* **FRANK LU**  
**PATENT EXAMINER**